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DOCUMENT 1-42/82

REPORT

on behalf of the Committee on the Environment, Public Health and Consumer Protection

on the proposal from the Commission of the European Communities to the Council (Doc. 1-857/80) for a directive laying down basic measures for the radiation protection of persons undergoing medical examinations or treatment

Rapporteur : Mrs B. WEBER

PE 76.879/fin.

1.2.1

English Edition

By letter of 29 January 1981 the President of the Council of the European Communities asked the European Parliament for its opinion on the proposal from the Commission of the European Communities to the Council for a directive laying down basic measures for the radiation protection of persons undergoing medical examinations or treatment.

On 9 February 1981 the President of the European Parliament referred this proposal to the Committee on the Environment, Public Health and Consumer Protection.

On 16 December 1980 the President of the European Parliament referred a motion for a resolution, tabled by Mrs Krouwel-Vlam pursuant to Rule 25 of the old Rules of Procedure (Doc. 1-716/80) on safety checks on medical apparatus, to the Committee on the Environment, Public Health and Consumer Protection.

On 26 February 1981 the Committee on the Environment, Public Health and Consumer protection appointed Mrs Beate WEBER rapporteur. It also decided to consider the proposal for a directive and the motion for a resolution together. It considered the proposal for a directive and the motion for a resolution at its meetings of 4 December 1981 and 17 and 18 March 1982 and adopted the proposal for a directive by 13 votes with 3 abstentions and the motion for a resolution by 16 votes to 3 at the latter meeting.

The following took part in the vote:

Mr McCartin, acting chairman; Mr Johnson, vice-chairman, Mrs Weber, vice-chairman and rapporteur; Mr Alber, Mr Berhouwer, Mr Bombard, Mr Combe, Mr Del Duca, Mr Ghergo, Mrs Van Hemeldonck, Miss Hooper, Mrs Lentz-Cornette, Mr Muntingh, Mrs Pantazi, Mrs Schleicher, Mrs Seibel-Emmerling, Mr Sherlock, Mrs Spaak and Mrs Squarcialupi.

CONTENTS

The Committee on the Environment, Public Health and Consumer Protection hereby submits to the European Parliament the following amendments and motion for a resolution together with explanatory statement:

Amendments by the Committee on the Environment, Public Health and Consumer Protection	Text proposed by the Commission of the European Communities[1]
AMENDMENT No.1	
Preamble, 5th recital:	
Whereas measures which make it possible to increase significantly the radiation protection of patients (delete five words) in no way jeopardize the benefits - whether early recognition, diagnosis or therapy - obtainable from radiation; whereas, on the contrary, measures which avoid inappropriate or excessive radiation levels improve the quality and effectiveness of medical uses of radiation.	Whereas measures which make it possible to increase significantly the radiation protection of patients and of the general public in no way jeopardize the benefits - whether diagnostic, preventive or therapeutic - obtainable from radiation; whereas, on the contrary, measures which avoid inappropriate or excessive radiation exposure improve the quality and effectiveness of medical uses of radiation;
AMENDMENT No. 2	
Preamble, 9th recital (new):	
Whereas the Member States will also take into account the results achieved to date by the five-year EAEC research and training programme in the field of biology-health protection adopted by the Council.	
AMENDMENT No. 3	
Article 1, paragraph 2:	
Assistants, including technical staff, shall receive instruction in the techniques applied and in suitable radiation protection procedures; they shall receive training appropriate to their work.	Assistants shall receive instruction in the techniques applied and in suitable radiation protection procedures; they shall receive training appropriate to their work.
AMENDMENT No. 4	
Article 1, paragraph 3 (new):	
'Doctors and assistants shall at regular intervals update their knowledge of new means of radiation protection.'	
AMENDMENT No. 5	
a) No radiological examination shall be carried out without medical indication;	(a) No radiological examination shall be carried out for preventive purposes without medical indication;

[1] OJ No. C 350 of 31.12.1980

AMENDMENT No. 6

Article 2, Paragraph b):

(b) Individual or collective preventive radiological examinations shall be carried out only if they are biologically, clinically or epidemiologically justified; they shall be carried out as infrequently as possible; alternative measures shall be developed and permitted.	(b) Individual or collective preventive radiological examinations shall be carried out only if they are biologically, clinically or epidemiologically justified;

AMENDMENT No. 7

Article 2, Paragraph d):

'(d) Direct fluoroscopic examinations without the use of image intensification shall be carried out only in medical emergencies. In the diagnostic use of radiation, care shall be taken to ensure that the image-recording systems used in fluoroscopic examinations, x-ray photography and examination methods involving measurement systems (computer tomography, Gamma-camera examinations) are so designed that the radiation dose required to produce the image is as low as it can be while still furnishing the desired information.	(d) Direct fluoroscopic examinations without the use of image intensification shall be carried out only when justified by exceptional circumstances.

AMENDMENT No. 8:

Article 2, paragraph e) (new):

e) In nuclear medical examinations, long-lived radionuclides should be replaced by short-lived radionuclides wherever this is medically and economically acceptable.

AMENDMENT No. 9

Article 4:

The doctors or dentists engaged in radiology and assistants referred to in Articles 1 and 3 shall make the necessary arrangements to ensure that the exposures required for diagnostic purposes are kept as low as possible.	The doctors or dentists engaged in radiology and assistants referred to in Article 1 and 3 shall make the necessary arrangements to ensure that exposures permitted for diagnostic purposes are kept under control and as low as reasonably achievable.

AMENDMENT No. 10

Article 5, paragraph (a) :

(a) 'Member States shall set up an informal system allowing the doctor who subsequently treats a patient to ascertain the nature and extent of the previous radiological examinations he has undergone : the technical data may also be recorded on the X-Ray itself.' Before requesting an examination the doctor responsible shall make sure that the information he requires was not provided by previous examinations.	(a) Member States shall set up a system allowing any practitioner who may be consulted to ascertain what previous radiological examinations a patient has undergone.

AMENDMENT No. 11

Article 6, paragraph 1 :

Member States shall establish (11 words deleted) criteria of acceptability for radiological installations, without prejudice to the Community provisions on harmonization relating to medical electroradiological equipment.	Member States shall draw up an inventory of medical and dental radiological equipment and shall establish criteria of acceptability for radiological installations, without prejudice to the Community provisions on harmonization relating to medical electroradiological equipment.

AMENDMENT No..12

Article 6, paragraph 2 :

'All installations in use shall be kept under appropriate surveillance at regular intervals to be laid down, in regard to the procedures applied and their radiation levels.	All installations in use shall be kept under appropriate surveillance in regard to procedures relevant to radiological protection.

AMENDMENT No. 13

Article 6, paragraph 3 :

Installations which meet the criteria established pursuant to paragraph 1 shall bear a seal of approval	
Member States shall implement the necessary measures with a view to improving inadequate or defective features of installations subject to such surveillance. Member States shall ensure that all installations which no longer meet the criteria established in accordance with paragraph 1 are taken out of service. or replaced within six months.	Member States shall implement the necessary measures with a view to improving inadequate or defective features of installations subject to such surveillance. In extreme cases Member States may require that certain installations be removed from service.

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MOTION FOR A RESOLUTION

embodying the opinion of the European Parliament on the proposal from the Commission of the European Communities to the Council for a directive laying down basic measures for the radiation protection of persons undergoing medical examinations or treatment

The European Parliament,

- having regard to the proposal from the Commission of the European Communities to the Council (COM(80)821 final)[1],
- having been consulted by the Council (Doc.1-857/80),
- on the basis of the EAEC Treaty, in particular Article 2 (protection of the health of workers and the general public) and Article 30 (protection of the general public against the dangers of radiation),
- having regard to the Council directive laying down the basic safety standards for the health protection of the general public and workers against dangers of ionizing radiation of 15 July 1980[2],
- whereas the present proposal for a directive must be assessed in the light of the directive on protection against the dangers of microwave radiation adopted by the Council and the five-year research and training programme in the field of biology and health protection against ionizing radiation,
- having regard to the opinion of the Economic and Social Committee of 3 July 1980[3],
- having regard to Recommendations Nos. 15, 16 and 26 of the International Commission on Radiological Protection (ICRP),
- having regard to the motion for a resolution tabled by Mrs Krouwel-Vlam on safety checks on medical apparatus (Doc. 1-716/80),
- having regard to the report of the Committee on the Environment, Public Health and Consumer protection, (Doc, 1-42/82).

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[1] OJ No. C 350 of 31.12.1980

[2] OJ No. L 246 of 17.9.1980

[3] OJ No. C 230 of 8.9.1980

1. Recognizes the potential of radiation in relation to the early recognition, diagnosis and therapy of human diseases;

2. Draws attention, however, to the fact that all excessive exposure to radiation must be avoided;

3. Requests therefore that medical grounds should be the prime condition for radiological examinations; examinations for the purposes of industrial medicine and insurance should be avoided as far as possible; examinations aimed at controlling epidemics should be kept to the essential minimum;

4. Insists that care be taken that the diagnostic or theraputic aim pursued is achieved with as low a radiation level as possible;

5. Advocates an informal information system on the radiological examinations carried out in the interests of the general public; details of these examinations could be recorded for example in vaccination certificates or other health cards already available and should indicate both the level of radiation and the nature of the tests performed;

6. Requests in addition that, as a first step, information on the radiological examinations carried out on a patient must be passed on to the relevant doctor concerned in order to avoid multiple exposures;

7. Considers that good training and further training in radiology for doctors and assistants is essential for the protection of the general public against unnecessary radiological examinations;

8. Calls on the Commission to consider whether permission to operate such radiological apparatus can be made uniformly conditional throughout the Community on evidence of appropriate training;

9. Doubts the value of the custom in several Member States of practices not specializing in radiology being equipped with standard radiological apparatus;

10. Supports, on these grounds and with a view to reducing costs, the request that technically complex and costly equipment should be located in central establishments with qualified staff;

11. Calls for the use of apparatus of the highest current scientific and technical standard in order to keep the exposure of patients to radiation down to a minimum;

12. Considers that strict regular servicing of all equipment in use is essential and requests that equipment which has been tested should be labelled with a test mark;

13. Considers it necessary for radiotherapy centres to use the services of radiologists to monitor and ensure dosimetric accuracy, the alignment and correct calibration of radiological equipment and the proper functioning of such apparatus;

14. Considers it necessary for the Commission to promote a comprehensive and coordinated research policy with regard to all forms of radiation and, in the short term at least, the coordination of current measures in individual sectors;

15. Approves the proposal for a directive subject to the amendments which have been adopted and requests the Council to adopt these amendments pursuant to Article 31 of the Treaty establishing the European Atomic Energy Community.

EXPLANATORY STATEMENT

1. The genetically significant exposure of the general public to radiation is composed mostly of natural radiation (approximately 110 millirem per annum) and to a lesser extent of artificial radiation (approximately 60 millrem per annum).

2. Artificial radiation, in its turn, arises chiefly through the use of ionizing radiation and radioactive substances in medicine, radio diagnostics accounting for the major part with approximately 50 millirem per annum, whilst radiotherapy and nuclear medicine each account for less than one millirem per annum[1].

3. It is clear from these figures that radiation levels must be reduced chiefly in connection with medical treatment. Several international organizations, such as the United Nations Scientific Committee on the Effects of Atomic Radiation, the World Health Organization and the International Commission on Radiological Protection, have drawn up recommendations in this respect.

4. The jurisdiction of the European Community in relation to radiation protection is based on Article 2 of the EAEC Treaty which provides that the protection of the health of workers and of the general public is a task of the Community, whilst Article 30 thereof refers in particular to the protection of the general public against dangers arising from radiation.

5. In the directive laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation of 15 July 1980 final provisions are laid down for the radiation protection of medical workers. This proposal for a directive, which is intended to lay down provisions for the protection of the whole population against radiation exposure at Community level, must therefore be regarded as completing the former directive.

6. The present proposal for a directive forms part of the Community's policy on protection from all types of radiation. It should be grouped together, from the point of view of subject matter, with the Council directive on the health protection of workers and the general public against the dangers of microwave radiation and the five-year research and training programme of the EAEC in the field of biology - Health Protection.

7. The benefits of ionizing radiation in the early recognition, diagnosis and therapy of diseases are essentially undisputed but it is nevertheless necessary to ensure that the advantages of diagnostic radiology are achieved with the minimum risk to individuals and future generations (ICRP).

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[1] Quotations from: German Bundestag, Document 9/644 of 8 July 1981 (Umweltradioaktivität un Strahlenbelastung im Jahre 1979) (Environmental Radioactivity and Radiation in 1979);similar data are given by the International Atomic Energy Authority in Vienna in 'Les Rayonnements - Données de l'existence'(Radiation-existence data), Vienna 1979.

8. In addition every intentional radiation exposure, including X-ray examinations in diagnostics, should be justified by the anticipated benefits of the treatment necessitating radiation exposure, a request made by the International Commission on Radiological Protection as long ago as 1973.

9. Improved use of radiation, in other words a reduction in the radiation level without a loss in diagnostic information, may be achieved by three measures:

(a) an improvement in the technical knowledge of doctors, dentists and their assistants engaged in radiology;
(b) more stringent grounds in the relevant medical procedure;
(c) technical improvements in the equipment used.

10. The importance of an improvement in the technical knowledge of doctors, dentists and their assistants who are engaged in radiology may be made clear by a few examples:

11. K.Z. Morgan showed as long ago as the 1960s that the average exposure of the general public as a result of medical treatment could be reduced by a factor of 10 by improved training of doctors and assistants in radiation protection[1].

12. The Government of the Federal Republic of Germany has shown in its report on 'Environmental Radioactivity and Radiation in 1978' that radiation exposure may still produce differences of more than 1 to 100 per examination method as a result of different radiographic materials, the number of exposures per examination and the length of fluoroscopic examinations.[2]

13. The ICRP pointed out very early on the danger arising from the spread of diagnostic radiological equipment to general practices and to non-specialists. In some Member States this equipment is regarded as being almost standard equipment.

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[1] K.Z Morgan: Ionizing radiation: Benefits versus Risks, Health Physics, Pergamon Press 1969, Vol. 17

[2] Bundestag Document 8/4101 of 22 May 1980

14. The growth rate in the number of radiographs in the Community is at present approximately 10% per annum and on average 3 to 5 instead of 1 to 2 radiographs are taken per patient because the equipment is easier to operate, although the apparatus is constantly improving. It is assumed that full use cannot be made of most of the radiographs because doctors and operators have insufficient knowledge of their potential uses.

15. Training in radiodiagnostics, radiotherapy or nuclear medicine for all doctors, dentists and assistants engaged in radiology would therefore, in the unanimous opinion of all experts, considerably reduce the radiation exposure of the general public in the field of medicine. This technical knowledge should however not be certified merely by attendance certificates but should also be examined with regard to substance.

16. Improved technical knowledge will also mean that each procedure is carefully chosen, in other words radiation exposure of the patient should be justified on very stringent medical grounds indicating such treatment.

17. Mass radiology for insurance or industrial medical purposes should be regarded in a very critical light since the advantages gained from them could also in some instances be obtained by other measures, and these advantages generally bear no reasonable relation to the risk incurred by the patient exposed to radiation[1].

18. Precise information as to radiation exposures to which a person has already been subject is an essential requirement to enable doctors to reach a responsible decision. For this reason an information system is necessary in order to be able to ascertain precisely the kind and number of radiation exposures to which the patient has been subject.

19. This information system should not give rise to further bureaucracy; it should be possible to include it in the relevant national procedure, for example, in the German vaccination certificate or in the form of a radiograph booklet such as the French 'carte individuelle radiologique' (personal radiology card)[2].

20. Technical improvement of equipment is also likely to produce a considerable reduction in radiation exposure.

21. The regular surveillance of all radiological equipment in use should (as in the case of motor cars) be compulsory. Old and unserviceable equipment which is not in keeping with the latest technology should be withdrawn, and equipment which exposes patients to a lower radiation level should be compulsorily introduced within a fixed period.

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[1] See also ICRP information of 18.7.1973 to all Members entitled 'Statement on trends in diagnostic radiology'

[2] See also World Health Organization, Geneva, 'Manual on Radiation Protection in Hospitals and General Practice'

22. In this connection the examples of image intensifiers with television cameras and monitors may be mentioned. These enable the radiation to be reduced by a factor of 2 or 3, but are not yet available everywhere.

23. Operation of equipment without an intensifying screen, as is, for example, often the case with mammography, could immediately be prohibited in all Member States. There are no technical problems in this connection.

24. The use of radiation could be optimized by setting up central establishments in which technically complex and costly equipment could be installed and would be operated by trained staff, thus providing the best guarantee for the highest radiation protection.

25. It seems, from a comparison of the examination figures from the United Kingdom and the Federal Republic of Germany annexed to this report[1] that there is a further factor which may reduce the exposure of the general public to radiation, in other words the method of reimbursement of costs. Wall and Kendall[2] state in their report that the number of patients referred for radiological examinations in the United Kingdom is so small because of financial restrictions too and that this number may well increase if the financial restrictions are lifted. On the other hand, radiological examinations rate high in the scale of doctors' fees in the Federal Republic of Germany; if the rate for such examinations were different perhaps some of them would not be carried out.

26. The number of radiographic examinations carried out may indeed indicate the efficiency of the health system; however, doubts are still justified as to whether such great differences as these between the Federal Republic of Germany and the United Kingdom really reveal the difference in the quality of the medical care of the general public.

27. The rapporteur wishes to thank the Head of the Central Department for Radiation Protection and Dosimetry of the German Cancer Research Centre in Heidelberg, Mr Otto Krauss, for his expert advice.

[1] See page 13 (Annex I)

[2] B.F.Wall and G.M. Kendall in 'Medical Radiology and Population Exposure' (National Radiological Protection Board, Harwell 1980)

ANNEX 1

Comparison of the number of radiographic examinations in the Federal Republic of Germany and the United Kingdom radiographic examinations per thousand of the population in 1978 or 1977) and in some other industrialized countries.

1. Federal Republic of Germany (1978).

Radiographic examinations carried out in 1978 per 1000 of the population:

1400 on medical grounds (including 300 on dental grounds)
300 preventive examinations (industrial medicine services and mass examinations)
1700 radiographic examinations = approximately 100 million radiographic examinations in 1978 in terms of the total population of the Federal Republic of Germany.

During the course of these examinations 3.5 radiographs per person were taken on average.

2. United Kingdom (1977)

Radiographic examinations carried out in 1977 per 1000 of the population:

393 radiographic examinations in National Health Service hospitals
approximately 47 outside National Health Service hospitals
approximately 110 dental examinations
550 radiographic examinations = approximately 21.3 million radiographic examinations in 1977 in terms of the total population of the United Kingdom.

In the course of these examinations 2.4 radiographs were taken on average per person.

3. Number of radiographic examinations per 1000 of the population in industrialized countries

Country	Year	Examinations per 1000 of the population
Federal Republic of Germany	1974	1658
Switzerland	1971	1350
Netherlands	1972	1186
Japan	1974	810
USA	1970	669
Sweden	1974-76	650
United Kingdom	1977	440 (see above 550)

References:

1. Statistics provided by the Federal Health Office in Berlin 1978, Radiological Institute, quoted by O. Krauss in May 1980, German Cancer Research Centre, Heidelberg

2. B. F. Wall and G. M. Kendall in "Medical Radiology and Population Exposure"
(National Radiological Protection Board, Harwell 1980)

3. UNSCEAR 1977 Report to the General Assembly on the Source and Effects of Ionizing Radiation, New York, UN 1977.

ANNEX II

Explanation of the technical terms used

Term		Explanation
Dose equivalent	=	The product of absorbed dose and the valuation factor. The dose equivalent is the measure of the effects of ionizing radiation on human beings.
Exposure	=	Any exposure of persons to ionizing radiation.
Dose	=	The quantity of radiation from a source of radiation which is absorbed by the human body.
Genetically significant dose	=	Enables an assessment of the effects on the genes.
Ionizing radiation	=	Electromagnetic or particulate radiation capable of producing ions (for instance alpha rays, beta rays, gamma rays and X-rays).
Nuclear medicine	=	the use of radioactive substances in medicine for diagnostic and therapeutic purposes.
Rem	=	Old dose-equivalent unit 1 rem = 1000 millirem
Radiation exposure	=	The effect of ionizing radiation on the human body or its parts.
Medical radiation exposure	=	the civilized exposure of persons to radiation as patients in connection with the medical uses of ionizing radiation and radioactive substances.

Explanations taken from:

Report of the Government of the Federal Republic of Germany on 'Environmental Radioactivity and Radiation Exposure'.

Thesis on terminology entitled 'Radiation Protection to Prevent Damage to Mankind' by U. Heimberger, Heidelberg, 1979.

ANNEX III

16 December 1980

DOCUMENT 1-716/80

MOTION FOR A RESOLUTION

tabled by Mrs KROUWEL-VLAM

pursuant to Rule 25 of the Rules of Procedure

on safety checks on medical apparatus

The European Parliament,

- whereas hospitals have in recent decades developed in structure to become highly specialized technical undertakings with the most modern equipment, so that many dangerous substances and extremely complicated medical apparatus are now to be found under one roof;
- whereas there been a large increase in the risk of accidents and medical complications due to the failure or malfunctioning of medical apparatus and/or the fauly operation of that apparatus, with all the attendant financial, social and psychological consequences;
- whereas the great diversity of medical apparatus and its often inefficient use make heavy demands on the sickness funds and/or social security systems of public health services;
- whereas part of the Community's task is to take measures to remove technical barriers to trade and to protect the consumer and patient;

1. Expresses its opinion that measures must be taken as soon as possible to protect the consumer, patient and the worker in the health care sector;
2. Considers that European type approval for medical apparatus and a procurement policy by the health care institutions based thereon would further the cause of safety and could produce savings;
3. Requests the Commission to prepare a proposal to this effect and to submit it to the Council of Ministers.